DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

CIVCO Medical Instruments Co., Inc. d/b/a CIVCO Medical Solutions
% Ms. Amanda Stahle
Regulatory Affairs Specialist
102 First Street South
KALONA IA 52247

January 23, 2015

Re: K143396
Trade/Device Name: omniTRAX™ Active Patient Tracker
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, LNH
Dated: November 21, 2014
Received: November 26, 2014

Dear Ms. Stahle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K143396

Device Name: Active Fiducial Marker

Indications for Use: The device is intended to provide physicians with a tool for electromagnetic (EM) tracking of instruments with respect to pre-acquired or real-time data. The device is intended for use in Magnetic Resonance Imaging (MRI) and ultrasound (US) environments.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K143396

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# Section 5 – 510(k) Summary

## A. Submitter Information

| | |
|---|---|
| Submitter Name & Address: | CIVCO Medical Instruments Co., Inc.<br>d/b/a CIVCO Medical Solutions<br>102 First Street South<br>Kalona, IA 52247 |
| Contact Person: | Amanda Stahle, Regulatory Affairs Specialist<br>Telephone: 319-248-6628, Fax: 877-218-0324<br>amanda.stahle@civco.com |
| Date Summary Prepared: | November 21, 2014 |
| Trade Name: | omniTRAX™ Active Patient Tracker |
| Common Name: | Active Fiducial Marker |
| Classification Names & Numbers: | System, Imaging, Pulsed Echo, Ultrasonic (892.1560)<br>System, Nuclear Magnetic Resonance Imaging (892.1000) |
| Device Class: | Class II |
| Review Panels: | Radiology |
| Product Codes: | IYO, LNH |

## B. Predicate Device

The proposed device is substantially equivalent to the following predicate device:

| Predicate Device | Manufacturer |
|---|---|
| Active Fiducial Marker in K092619 Electromagnetic Tracking System | CIVCO Medical Instruments Co., Inc. |

The purpose of this 510(k) is to expand the indications for use of the proposed device to include use in the MR environment and update the device design. CIVCO has conducted MR safety and compatibility testing to confirm that the proposed device can be safely used in the MR environment.

## C. Device Description

The proposed device contains multiple fluid-filled cavities that serve as registration points (markers) in MR. Adhesive tape on the bottom of the proposed device is used to secure the device to the patient. Skin marking areas allow for repositioning in both MR and ultrasound environments. The device also provides a connection point for an electromagnetic sensor accessory.

The proposed device is provided non-sterile, is intended for single patient use, and is manufactured of non-magnetic materials. The following model is included in this submission:

| Part No. | Device Name |
|---|---|
| 610-1306 | omniTRAX™ Active Patient Tracker |

The proposed device enables automatic or manual image fusion of real-time ultrasound to previously acquired MR data sets. The proposed device may also be used to aid in image fusion of real-time ultrasound to previously acquired ultrasound data sets. The device is used in a healthcare facility/hospital.

## D. Indications for Use/Intended Use

The device is intended to provide physicians with a tool for electromagnetic (EM) tracking of instruments with respect to pre-acquired or real-time data. The device is intended for use in Magnetic Resonance Imaging (MRI) and ultrasound (US) environments.

## E. Comparison of Technological Characteristics

Technological characteristics that have changed between the proposed and predicate device include changes in design and materials. The proposed device consists of four fluid-filled markers positioned at specific locations whereas the predicate device consisted of a single fluid-filled marker. Both devices provide a mount area for attachment of an electromagnetic sensor accessory. The proposed device contains skin marking areas whereas the predicate device does not contain these areas. Different materials were used to manufacture the proposed device and were selected with MR safety and effectiveness considerations.

## F. Non-Clinical Testing

Non-clinical testing was completed to confirm that the proposed device is as safe and effective as the predicate device and to confirm that the changes in technological characteristics do not raise any new issues of safety or effectiveness. This included MR safety and compatibility testing in accordance with ASTM Standards F2182-11a, F2052-06, and F2213-06. Testing was also completed using ASTM Standard F2119-07, but modifications were made to accommodate the external use of the device (not implanted). The devices passed the acceptance criteria for RF heating, magnetic induced torque, and magnetically induced displacement force and demonstrate that the device is safe for use in the MR environment. Localized image artifact was observed, and information regarding location and size of the artifacts has been included in the Instructions for Use.

Biocompatibility testing was also completed for patient-contacting materials according to ISO 10993-5:2009/(R) 2014 and ISO 10993-10:2010. The device is intended for limited contact duration (<24 hours) for surface devices (skin).

## G. Conclusion

This premarket submission for the omniTRAX™ Active Patient Tracker has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.